IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Brazzell et al.
Appl. No.: 10/080,797
Conf. No.: 9942
Filed: 21 February 2002
Title: METHOD FOR TREATING OCULAR NEOVASCULARIZATION
Art Unit: 1635
Examiner: J. Angell
Docket No.: 116566-052

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO CORRECT INVENTORSHIP

Applicants respectfully request a correction of inventorship, to add Michael Kaleko and Tianci Luo as co-inventors of the instant application.

STATEMENT OF FACTS

1. While reviewing an Office Action and considering filing a Declaration as an inventor, Dr. Kaleko was advised he is not named as a co-inventor of the above-captioned application.

2. Dr. Kaleko was surprised and indicated that was an error.

3. Drs. Kaleko and Luo were involved in the invention described in the instant application, including, for example, being co-inventors in the development of viral vectors, such as lentiviral vectors, such as bovine immunodeficiency virus viral vectors.

4. At the least, because lentiviral vectors are claimed, Drs. Kaleko and Luo need to be added as co-inventors. Drs. Kaleko and Luo developed the lentiviral endostatin vector.

POINTS TO BE REVIEWED

1. The error in Dr. Kaleko and Dr. Luo not being named as co-inventors of the above-captioned application was an oversight and occurred without deceptive intent on their part.

2. Drs. Kaleko and Luo are co-inventors of subject matter claimed in the instant application and must be added to the inventive entity thereof.

RELIEF REQUESTED

1. It is respectfully requested that Michael Kaleko and Tianci Luo be added as co-inventors.

2. Attached hereto are Declarations from both Dr. Kaleko and Dr. Luo averring that the error occurred without deceptive intent.

3. A partially executed Declaration is attached hereto. The fully executed document will be submitted as soon as possible.

4. The processing fee under §1.17(i) of $130 is enclosed.

Favorable consideration and grant of the Petition are requested respectfully.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY

Dean H. Nakamura
Reg. No. 33,981
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (202) 955-6851

Dated: 8 February 2006

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DECLARATION OF MICHAEL KALEKO

I, Michael Kaleko, am a co-inventor of the above-captioned application.

The error of inventorship occurred without deceptive intent on my part.

All statements made herein of my own knowledge are true and that all statements made on information and belief are true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent application in the United States of America or any patent issuing therefrom.

Feb. 7, 2006
Date

Michael Kaleko

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DECLARATION OF TIANCI LUO

I, Tianci Luo, am a co-inventor of the above-captioned application.

The error of inventorship occurred without deceptive intent on my part.

All statements made herein of my own knowledge are true and that all statements made on information and belief are true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent application in the United States of America or any patent issuing therefrom.

Feb. 7, 2006
Date

Tianci Luo
Tianci Luo

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD FOR TREATING OCULAR NEOVASCULARIZATION

the specification of which: (check one)

☐ is attached hereto.

☒ was filed on 21 February 2002, as United States Application No. or PCT International Application No. 10/080,797
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent Office all information which is known to me to be material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code Section 119 or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT international application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Number	Country	Day/Month/Year Filed	Priority Not Claimed
			☐
			☐
			☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

Application Serial No.	Filing Date
60/270,787	22 February 2001
60/281,296	4 April 2001

I hereby claim the benefit under 35 U.S.C. Section 120 of any United States application(s), or Section 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C.F.R., Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

And I hereby appoint the practitioners at customer number:

29180

as my attorneys with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith and direct that all correspondence be forwarded to the address associated with customer number:

29180

Full name of sole or first inventor **Romulus Kimbro Brazzell**	
Sole or first inventor's signature	Date
Residence **Morrisville, North Carolina**	
Citizenship **USA**	
Post Office Address **127 Grande Drive**	
Morrisville, North Carolina 27560	

Full name of second inventor **Peter Anthony Campochiaro**	
Second inventor's signature	Date
Residence **Baltimore, Maryland**	
Citizenship **USA**	
Post Office Address **920 West Lake Avenue**	
Baltimore, MD 21210	

Full name of third inventor **Katharine Hilary Dixon**	
Third inventor's signature	Date
Residence **Olney, Maryland**	
Citizenship **United Kingdom**	
Post Office Address **2519 Little Vista Terrace**	
Olney, MD 20832	

Full name of fourth inventor **Michael Kaleko**
Fourth inventor's signature  Date Feb. 7, 2006
Residence **Rockville, Maryland**
Citizenship **USA**
Post Office Address **8 Hearthstone Court**
Rockville, MD 20854

Full name of fifth inventor **Tianci Luo**
Fifth inventor's signature Tianci Luo Date Feb. 7, 2006
Residence **Clarksville, Maryland**
Citizenship **USA**
Post Office Address **6512 Tipperary Court**
Clarksville, MD 21029

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DECLARATION OF MICHAEL KALEKO

I, Michael Kaleko, do hereby declare and state:

1. I have conducted research in gene therapy for 20 years.

2. I have conducted research in treating ocular diseases for 9 years.

3. I was involved in the development and use of lentiviral vectors for delivering genes to the eye.

4. I was involved in choosing endostatin as a gene to deliver to mouse retinas via a lentiviral vector.

5. Due to all of the negative data surrounding endostatin, there was neither enthusiasm nor interest in evaluating the use of endostatin to treat ocular diseases. The choice of endostatin was based solely on the availability of the cDNA construct. Specifically, at the time of the choice to use endostatin, I was employed at Genetic Therapy, Inc. (GTI), a wholly owned subsidiary Novartis. My colleagues in the oncology programs at GTI had recently used an adenoviral vector to evaluate endostatin in mouse tumor models and found it to be non-efficacious. Our first choice of a potential therapeutic for the ocular work was a soluble form of the VEGF receptor, known as sFlt, which was known to be a potent anti-angiogenic factor.

However, a sFlt construct was not available and there was significant pressure to rapidly generate data for an upcoming Novartis Portfolio Review (in which GTI research was critically reviewed and research efforts were sometimes discontinued). To rapidly generate ocular data for the Portfolio Review and thereby establish funding for future ocular studies, we opted to do the first experiment with the available endostatin construct. None of the researchers expected it to work in a mouse model of angiogenesis. We were resigned to use endostatin as a reporter gene. Specifically, we did not know and wanted to determine if our lentiviral vector could deliver a gene to the retina with sufficient efficiency to achieve expression of a secretable protein and achieve diffusion of that protein throughout the retina. We used immunohistochemical staining of endostatin to determine if the secreted endostatin would diffuse throughout the entire retina.

6. It is not an understatement to say that we were shocked when we learned from Dr. Campochiaro that in his model of VEFG-induced angiogenesis, endostatin lentiviral vector was efficacious in blocking neovascularization. It is also not an understatement that we rushed back to Gaithersburg to show the data to Dr. Edward Otto, the Chief Operating Officer of GTI. Those data led to the creation of the Ocular Gene Therapy Program at GTI. The data were so persuasive, that the program was funded by the Ophthalmics Therapeutic Area, a Novartis group that was unrelated to GTI.

7. We duplicated the experimentation to confirm the unexpected observation that lentiviral vector-delivered endostatin had an anti-angiogenic activity in the eye.

8. After establishing the GTI Ocular Program, we convened a Scientific Advisory Board (SAB) of ten prestigious experts in angiogenesis, ocular neovascularization, and ocular gene therapy. When shown the data, all the outside experts were significantly surprised, and in some cases, quite perplexed. Despite the data, several of the SAB members suggested that we

pursue an anti-angiogenic agent other than endostatin based solely on the rationale that endostatin does not work in cancer.

9. In summary, endostatin was a choice of convenience. The data that endostatin was efficacious in a mouse model of angiogenesis were shocking to us. Finally, endostatin had such a bad reputation in the cancer field that our ocular SAB was still not unanimous in suggesting we pursue its clinical application.

All statements made herein of my own knowledge are true and that all statements made on information and belief are true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent application in the United States of America or any patent issuing therefrom.

Feb. 7, 2006
Date

Michael Kaleko, M.D., Ph.D.